UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/518,098	03/03/2000	Leland Shapiro	114232.107	5420

27160 7590 12/05/2001

PATENT ADMINSTRATOR
KATTEN MUCHIN ZAVIS
SUITE 1600
525 WEST MONROE STREET
CHICAGO, IL 60661

EXAMINER	
LUKTON, DAVID	
ART UNIT	PAPER NUMBER
1653	18

DATE MAILED: 12/05/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/518,098	Shapiro
Examiner	**Art Unit**
David Lukton	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) [X] Responsive to communication(s) filed on *Nov 21, 2001*

2a) [ ] This action is **FINAL.** 2b) [X] This action is non-final.

3) [ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) [X] Claim(s) *1-45* is/are pending in the applica

4a) Of the above, claim(s) *1-39 and 43-45* is/are withdrawn from considera

5) [ ] Claim(s) _____ is/are allowed.

6) [X] Claim(s) *40-42* is/are rejected.

7) [ ] Claim(s) _____ is/are objected to.

8) [ ] Claims _____ are subject to restriction and/or election requirem

Application Papers

9) [ ] The specification is objected to by the Examiner.

10) [ ] The drawing(s) filed on _____ is/are objected to by the Examiner.

11) [ ] The proposed drawing correction filed on _____ is: a) [ ] approved b) [ ] disapproved.

12) [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) [ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) [ ] All b) [ ] Some* c) [ ] None of:

1. [ ] Certified copies of the priority documents have been received.
2. [ ] Certified copies of the priority documents have been received in Application No. _____.
3. [ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) [ ] Notice of References Cited (PTO-892)

16) [ ] Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) [X] Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) [ ] Interview Summary (PTO-413) Paper No(s). _____

19) [ ] Notice of Informal Patent Application (PTO-152)

20) [ ] Other:

Applicants' elections are acknowledged:

(a) group 13, claims 40-42, drawn to drawn to a method of treating a viral infection but which is limited to G1;

(b) *alpha*-1-antitrypsin as the specific compound that exhibits "AAT or AAT-like activity";

(c) retrovir as a compound falling within the scope of a "HIV reverse transcriptase inhibitor" or an "HIV protease inhibitor".

Applicants have traversed the second election of species requirement by implying that if an applicant waits until after the first Office action on the merits (FAOM) to list species, he acquires "immunity" from an election of species requirement. However, this is not true. Notwithstanding what may be stated in the MPEP, examiners are encouraged to impose a restriction/election prior to a FAOM, rather than afterwards. However, if applicants would argue that the MPEP should be controlling, the fact is that the MPEP does not preclude an examiner from imposing an "election of species" requirement after the FAOM, in response to an amendment. Applicants have not yet explained how they would have benefitted had this course of action been followed; it is not apparent that applicants would have benefitted by deferring the "election of species" requirement. Moreover, in the event that applicants choose not to list specific compounds that exhibit "AAT or AAT-like activity", this particular "election of species" requirement will be rendered moot.

*

This application contains sequence disclosures that are encompassed by the definitions for amino acid sequences set forth in 37 CFR 1.821. However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 with regard to the sequence disclosures.

Amendment of the specification is required, to list SEQ ID NOS (see, e.g., page 10)

*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims encompass a method of treating HIV infections in humans. However, applicant's *in vitro* experiments do not enable this extrapolation. As stated in *Ex parte Forman* (230 USPQ 546, 1986) the factors to consider in evaluating the need (or absence of need) for "undue experimentation" are the following: quantity of experimentation necessary, amount of direction or guidance presented, presence or absence of working examples, nature of the invention, state of the prior art, relative skill of those in that art,

predictability or unpredictability of the art, and breadth of the claims. As stated in Mangos (*Texas Medicine*, **86**, 40, 1990):

> "In spite of ... [therapy against HIV and opportunistic infections], the universal outcome of HIV infection / AIDS is the death of the patients" (see, e.g., abstract).

As disclosed in Binquet (*AIDS* **12**, 2313, 1998) a total of 556 patients were treated with HIV protease inhibitors for a period of 230 days, and that despite being treated with with HIV protease inhibitors for more than seven months, 24 of the patients had died. Both of these references teach that death occurs in spite of administration of HIV protease inhibitors. If death is the result of a treatment, one cannot say that success (in the treatment) is predictable. If sucess is not predictable, it must be "unpredictable". Given that treatment of AIDS is "unpredictable", it follows therefrom that "undue experimentation" would be required to determine which, if any, of the claimed compounds can be used to treat patients afflicted with AIDS. [*Ex parte Balzarini,* 21 USPQ2d 1892)]. Thus, extrapolation from *in vitro* inhibition of viral replication in a petri dish to a therapy in humans is unpredictable.

Either (or both) of the following is suggested:

> *A method of inhibiting human infectivity virus (HIV) replication in a host harboring HIV comprising administering to the host a combination of .... for a time and under conditions effective to inhibit HIV replication.*

> *A method of inhibiting human infectivity virus (HIV) replication comprising administering to a human patient in need thereof a combination of .... for a time and under conditions effective to inhibit HIV replication.*

*

Claims 40-42 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 40 recites the abbreviations "HIV" and "AAT". These abbreviations may be used, but only if accompanied by the full name of the terms which they represent.

- Claim 40 recites that a compound can exhibit an activity which is somehow "like" that of α1-antitrypsin. This renders the claims indefinite as to the manner in which and the extent to which, the compound must resemble α1-antitrypsin.

- Claim 40 is drawn to a method of treating an HIV infection in a "host". A host, however, could be a single cell, or a cell culture. A claim which recites a method of treating an HIV infection will remain rejected under §112, first paragraph, but that is not the point. The point is that if the host is a single cell, the term "treating" is not appropriate. The term "treating" would apply to human an animals (were it the case that other animals could become infected with HIV), and conveys that some improvement in the condition of the human or animal will ensue. However, in the case of a cell culture, what does it mean to "treat" an HIV infection? It is suggested that the claim be limited to humans, together with whichever animals applicants believe can become infected with HIV.

- Claim 41 is indefinite as to the process steps and endpoint. Were it the case that "treating an HIV infection" were enabled, the following would be suggested:

  A method of treating a human infectivity virus (HIV) infection comprising administering to a human patient in need thereof a combination of .... for a time and under conditions effective to inhibit HIV replication.

  Instead, either (or both) of the following is suggested:

  A method of inhibiting human infectivity virus (HIV) replication in a host harboring HIV comprising administering to the host a combination of .... for a time and

under conditions effective to inhibit HIV replication.

A method of inhibiting human infectivity virus (HIV) replication comprising administering to a human patient in need thereof a combination of .... for a time and under conditions effective to inhibit HIV replication.

- Claim 41 recites various trademark names. These may be used, but only if accompanied by the full name of the compounds that are represented. The same issue applies in the case of claim 42.

- Claim 41 recites that a reverse transcriptase inhibitor can be a combination of two or more of the recited agents. However, this is objectionable on grammatical and semantic grounds. A single inhibitor should not be equated with a multiplicity of inhibitors. The same issue applies in the case of claim 42.

*

The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claim 40 is rejected under 35 U.S.C. §103 as being unpatentable over Lezdey (USP 5,532,215).

Lezdey discloses (col 6, line 31) that serine protease inhibitors can inhibit HIV replication.

The reference also discloses one or more serine protease inhibitors that are asserted to have this property. The reference does not teach that the serine protease inhibitors are "like" α1-antitrypsin; the reference also does not teach combining a serine protease inhibitor with an "HIV reverse transcriptase inhibitor" or an "HIV protease inhibitor".

As indicated, the reference does not teach that the serine protease inhibitors are "like" α1-antitrypsin; however, the artisan of ordinary skill who is interpreting the term "AAT-like" very broadly would recognize that the disclosed serine protease inhibitors fall within the scope of the term at issue. As for HIV reverse transcriptase inhibitors and HIV protease inhibitors, these are well known to the virologist of ordinary skill; the virologist would have been motivated to combine the two for additive effects.

*

Claim 40 is rejected under 35 U.S.C. §103 as being unpatentable over Eisenberg (U.S.P. 6,017,880)

Eisenberg discloses (col 2, line 7+; col 2, line 20+) that serine leukocyte protease inhibitor can inhibit HIV replication. The reference does not teach that the serine protease inhibitor is "like" α1-antitrypsin; the reference also does not teach combining a serine protease inhibitor with an "HIV reverse transcriptase inhibitor" or an "HIV protease inhibitor".

As indicated, the reference does not teach that the serine protease inhibitor is "like" α1-antitrypsin; however, the artisan of ordinary skill who is interpreting the term "AAT-like" very broadly would recognize that the disclosed serine protease inhibitor falls within the

scope of the term at issue. As for HIV reverse transcriptase inhibitors and HIV protease inhibitors, these are well known to the virologist of ordinary skill; the virologist would have been motivated to combine the two for additive effects.

*

- Reference BB was stricken because the record should be made clear that only the abstract was considered. The following format could be used:
  Abstract of WO/98....
- Reference CI was stricken because of the absence of a translation.
- References CK, CBJ and CBE were stricken because of the absence of a translation.
- Reference CCY was stricken because only pages 1519 - 1544 were provided
- Reference CC was stricken because only the table of contents was provided.
- Reference CCZ (Sambrook) was stricken because only the table of contents was provided.
- The remaining references that were stricken (e.g., US Patents) were so treated because they were not received.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1600